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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,482	04/03/2001	Menashi A. Cohenford	CYM-035	2116

21323 7590 11/29/2002

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EXAMINER	
SIEW, JEFFREY	
ART UNIT	**PAPER NUMBER**
1637	7

DATE MAILED: 11/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/825,482	COHENFORD ET AL.	
	Examin r	Art Unit	
	Jeffrey Siew	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,15 and 16* is/are rejected.

7)☐ Claim(s) *13 and 14* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 April 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *stic report* 4/8

DETAILED ACTION

1. Applicant's election without traverse of Group I in Paper No. 6 is acknowledged. Applicant has cancelled claims 17-37. Pending claims are 1-16.

Claim Objections

2. For clarity in claim13 it is requested that each primer be separately referred to by their SEQ ID NO e.g. MY09((SE ID NO:10).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 6 is indefinite because it is unclear as to whether the probe differs in sequence or in one nucleotide. It is unclear as to what the probe is different from when the recitation in the claim appears to be referring to itself.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,2,5-8 &16 are rejected under 35 U.S.C. 102(b) as being anticipated by Steinman (US5,849,497 Dec. 15, 1998).

Steinman teach a method of detection of selected stain of an organisms comprising providing a sample that may comprise at least one selected and non selected strain, providing a plurality of primers complementary to regions of selected and non selected strain, exposing to at least one probe that is complementary to non selected strain in between primers and probe is nucleic acid analog, amplifying and detecting (see whole doc. esp. abstract & col.2 lines 4-55 & col. 1 line 40& 42). They teach a probes greater than 8 nucleotides (see Table I). They teach separation and detection by gel electrophoresis (see col. 10 lines 4-6).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3,4,9-12,[illegible] are rejected under 35 U.S.C. 103(a) as being unpatentable over Steinman (US5,849,497 Dec. 15, 1998) in view of Lancaster et al (US5,863,717 Jan. 26, 1999).

The teachings of Steinman are described previously.

Steinman do not teach HPV.

Lancaster et al teach PCR amplification of HPV(see whole document). They teach low risk strains HPV 6 & 11 and high risk HPV 16 & 18 (see col. 1 line 26 & 27). They teach the association with pathogenesis of cancer (see col. 1 lines 5-10).

One of ordinary skill in the art at the time the invention was made would have been motivated to apply Lancaster et al's primers to Steinman method of PCR in order to detect different strains of HPV. Lancaster et al teach that HPV infection has high correlation with cervical cancer. It would have been prima facie obvious to combine Steinman method of strain differentiation with Lancaster et al's primers in order to detect the high risk strains HPV in patients.

6. Claims 13 & 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steinman (US5,849,497 Dec. 15, 1998) in view of Mahoney et al (US6,045,993 April 4, 2000)

The teachings of Steinman are described previously.

Steinman do not teach SEQ ID NO:10 and 11 or cervical scrapings.

Mahoney et al teach PCR amplification with primers(see whole doc. esp. abstract). They teach primer of SEQ ID NO:1 which matches claimed SEQ ID NO:11. They teach primer SEQ ID NO:2 which matches claimed SEQ ID NO:10. They teach cervical specimens such as swabs and brushings, scrapings (see col.2 line 34).

One of ordinary skill in the art at the time the invention was made would have been motivated to apply Mahoney et al's primers to Steinman method of detection in order to amply HPV in sample. Mahoney teach the successful amplification with SEQ IDNO:1 & 2 (see example 1). It would have been prima facie obvious to apply Mahoney et al's teachings of primers to Steinman in order to successfully amplify HPV for detection.

SUMMARY

7. Claim 14 is objected to for depending on rejected claim. Claim 14 is free of the prior art. The closest prior art is Bauer et al who teach SEQ ID NO:21 which is 25 base pairs and used in probing HPV but Bauer et al explicitly state longer probes lead to less mismatches and give preferably sizes of 18-20 bases (see col. 9 lines 5-15). Moreover, Bauer et al do not teach or suggest the use of PNA blocker probes.

CONCLUSION

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number is (703) 305-3886 and whose e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Tracey Johnson for Art Unit 1637 whose telephone number is (703)-305-2982.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and Before Final FAX (703) 872-9306 or After Final FAX (703) 30872-9307.

JEFFREY SIEW
PRIMARY EXAMINER

November 26, 2002

Stic Report Seq 10467

RESULT 5
AAT77886
ID AAT77886 standard; DNA; 25 BP.
XX
AC AAT77886;
XX
DT 06-OCT-1997 (first entry)
XX
DE Human papillomavirus probe FS10.
XX
KW Human; papillomavirus; HPV; probe; detection; ss.
XX
OS Synthetic.
XX
PN US5639871-A.
XX
PD 17-JUN-1997.
XX
PF 09-SEP-1988; 88US-0243486.
XX
PR 24-SEP-1993; 93US-0126452.
PR 09-SEP-1988; 88US-0243486.
PR 10-MAR-1989; 89US-0322550.
PR 09-SEP-1989; 89WO-US03747.
PR 14-NOV-1990; 90US-0613142.
PR 20-APR-1993; 93US-0050743.
PR 01-JUN-1995; 95US-0457648.
XX
PA (HOFF) ROCHE MOLECULAR SYSTEMS INC.
XX
PI Bauer HM, Gravitt PE, Greer CE, Impraim CC, Manos MM;
PI Resnick RM, Zhang TY;
XX
DR WPI; 1997-332084/30.
XX
PT New oligo:nucleotide probes for human papilloma-virus - used for
PT detecting and typing HPV and for detecting previously unknown HPV
PT types and subtypes
XX
PS Disclosure; Columns 69-70; 94pp; English.
XX
CC The present sequence is a human papillomavirus (HPV) specific
CC probe.
XX
SQ Sequence 25 BP; 7 A; 7 C; 6 G; 5 T; 0 other;

  Query Match   100.0%; Score 17; DB 18; Length 25;
  Best Local Similarity   100.0%; Pred. No. 6.6;
  Matches   17; Conservative   0; Mismatches   0; Indels   0; Gaps   0;

Qy   1 TAGATACCACACGCAGT 17
           |||||||||||||||||
Db   7 TAGATACCACACGCAGT 23

STIC Report Seq ID No 6

RESULT 7
AAT77886
ID AAT77886 standard; DNA; 25 BP.
XX
AC AAT77886;
XX
DT 06-OCT-1997 (first entry)
XX
DE Human papillomavirus probe FS10.
XX
KW Human; papillomavirus; HPV; probe; detection; ss.
XX
OS Synthetic.
XX
PN US5639871-A.
XX
PD 17-JUN-1997.
XX
PF 09-SEP-1988; 88US-0243486.
XX
PR 24-SEP-1993; 93US-0126452.
PR 09-SEP-1988; 88US-0243486.
PR 10-MAR-1989; 89US-0322550.
PR 09-SEP-1989; 89WO-US03747.
PR 14-NOV-1990; 90US-0613142.
PR 20-APR-1993; 93US-0050743.
PR 01-JUN-1995; 95US-0457648.
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PT New oligo:nucleotide probes for human papilloma-virus - used for
PT detecting and typing HPV and for detecting previously unknown HPV
PT types and subtypes
XX
PS Disclosure; Columns 69-70; 94pp; English.
XX
CC The present sequence is a human papillomavirus (HPV) specific
CC probe.
XX
SQ Sequence 25 BP; 7 A; 7 C; 6 G; 5 T; 0 other;

  Query Match   100.0%; Score 15; DB 18; Length 25;
  Best Local Similarity   100.0%; Pred. No. 39;
  Matches   15; Conservative   0; Mismatches   0; Indels   0; Gaps   0;

Qy   1 AGATACCACACGCAG 15
           |||||||||||||||
Db   8 AGATACCACACGCAG 22